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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,656

11/28/2006

Rudi Mueller-Walz

28069-625N01US

2553

35437

7590

03/09/2011

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EXAMINER

KENNEDY, NICOLETTA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

03/09/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/575,656	Applicant(s) MUELLER-WALZ ET AL.	
	Examiner Nicoletta Kennedy	Art Unit 1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 February 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1, 3-7, 12-23.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

/N. K./
Examiner, Art Unit 1611

/Anne R Kubelik/
Primary Examiner, Art Unit 1638

Continuation of 11. does NOT place the application in condition for allowance because: The rejections of record are maintained. Applicant argues that Ventura teaches away from using magnesium stearate at an amount of 1.5% by weight (remarks, p. 5). Although this may teach one of ordinary skill in the art not to use magnesium stearate at this range, it does not teach away from using magnesium stearate in other amounts between 0.02 and less than 1.5%.

Applicant again relies on the teachings of Chiesi to state that less than 0.5% by weight magnesium stearate is used. However, Chiesi is not relied upon in the current rejections. Further, Staniforth explicitly teach amounts up to 1.5% by weight. No specific examples in Staniforth are necessary to demonstrate this because the text of Staniforth teaches it. This statement provides motivation for one of ordinary skill in the art to use ranges of magnesium stearate as taught by Staniforth.

With regard to the surface coverage of the carrier particles, Applicant argues that Vectura teaches higher coverage with less additive (remarks, p. 8). As stated in the final rejection, Vectura teach a powder where it is desirable to have a discontinuous coating of additive. Further, the mixing time is between 0.1 and 0.5 hours. Applicant quotes Vectura as saying "in the sense that even if more additive material were provided, substantially the same covering would be achieved" to show that a decreased degree of coating is not taught. However, that citation does not negate the teachings of a discontinuous coating. Additionally, the mixing time of Vectura is within the guidelines taught in the instant specification for achieving low surface coverage (p. 8).

Applicant next argues that unexpected results are shown in the instant specification at pages 21-24 yet does not explain any results other than to state that the examples of the instant invention have a reproducibly high fine particle fraction which is also stabilized against moisture (remarks, p. 8). However, the data explained in the instant specification does not compare the closest prior art nor is the data commensurate with the scope of the claims. The instant specification does not show unexpected results but states that magnesium stearate has a stabilizing effect on the fine particle fraction dry powder formulations. The art already used magnesium stearate and unexpected results would need to show why the surface coverage and amount of magnesium stearate are distinguished from the surface coverage and amounts of the prior art.

The remaining rejections are maintained because they depend on the rejection discussed above, which is also maintained

The double patenting rejections are held in abeyance.

Continuation of 13. Other: The claims are entered because they are a duplicate copy of the claims that were finally rejected.